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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/808,357 | 03/25/2004 | John E. Uschold | 12013/50601 | 5454 |

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| EXAMINER |
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AHMED, AAMER S

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| ART UNIT | PAPER NUMBER |
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3763

DATE MAILED: 09/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/808,357

Applicant(s)

USCHOLD, JOHN E.

Examiner

Aamer S. Ahmed

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 August 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3 and 5-23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3 and 5-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of Application

In a conversation with applicant's attorney's Jocelyn Ram and Zeba Ali, it was agreed that the finality of the office action mailed 05/19/2006 was improper as now cancelled independent claim 24 was not amended. Therefore applicant's amendments and arguments received 08/16/2006 have been entered and are addressed in the instant office action below.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2 and 6-10 rejected under 35 U.S.C. 102(b) as being anticipated by Vaslow U.S. Patent Number 4,453,641.

Vaslow ('641) discloses a needle (1) comprising a shaft (12) having a distal end (20) defining a distal opening (8) and having a longitudinal axis (18) extending through the distal opening, the distal opening (8) having a projected area that is smaller than a cross-sectional area of a section of the shaft (12) proximal to the distal end of the shaft (12), wherein the distal most end is a curvilinear distal tip (see line of curvature of 20 from point marked by 8 to point marked by 14 and inward arc), wherein the distal end comprises opposing first (9) and second (20) surfaces and the first surface (9) is indented towards the second surface (20); wherein the distal end comprises opposing first (9) and second (20) extensions, which are angled towards each other and the second extension (20) is longer than the first (9) in a direction parallel to the

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longitudinal axis (18) of the shaft (12) and these extensions (20) and (9) mutually define at least one opening (8) offset from the longitudinal axis (18) of the shaft (12). Furthermore, Vaslow ('641) discloses that the at least one opening (8) is a pair of openings (8), see figure 3 and the extensions (20) and (9) each terminate in beveled distal tips, see figure 1.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 3, 5 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vaslow in view of Alchas U.S. Patent Number 4,537,593.

Vaslow discloses the device as described above in reference to claim 1, but fails to explicitly disclose a port or that the distal end of the needle is tapered.

Alchas ('593) describes that the distal end of the shaft 26 comprises at least one port (36) on it's side, the distal end terminates in a curvilinear distal tip (31) and the distal end of the shaft

(26) is tapered, and the needle (20) being on the distal end of a syringe (117) see figures 1, 2 and 14.

It would have been obvious to one having ordinary skill in the art at the time of invention by the applicant to modify the device of Vaslow by incorporating the port and tapered shaft of the type taught by Alchas, in order to vent air and allow access to narrow target areas.

Claims 11 and 13-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vaslow in view of Altman U.S. Patent Number 6,346,099.

Vaslow discloses the device as described above in reference to claim 1, but fails to explicitly disclose a catheter and syringe attached to the needle, nor a method of using the needle to deliver a therapeutic agent.

Altman discloses a similar device and method of use. Altman ('099) discloses that the needle (312) is on the distal portion of a catheter (5). Moreover Altman ('099) teaches a method of delivering a therapeutic agent to a target site of a body comprising providing a drug delivery device (306) containing a therapeutic agent and comprising a needle (312) at a distal portion thereof; and delivering the therapeutic agent through the needle to a target site of a body (col. 3 line 18), wherein the drug delivery device is a catheter (5), the target site is the heart (col. 3 line 29), the method comprising of directly delivering the therapeutic agent to the target site (col. 3 line 22).

It would have been obvious to one having ordinary skill in the art at the time of invention by applicant to modify the device of Vaslow by incorporating the method of the type taught by Altman in order to deliver drugs to the heart.

Claims 17-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vaslow in view of Luther et al U.S. Patent Number 5,873,864.

Vaslow discloses the device as described above with reference to claim 1, but fails to explicitly disclose the method step of placing the needle in an access port.

Luther et al discloses a similar device and a method including inserting the needle of the drug delivery device (10) into a drug delivery port (32) to access the drug delivery port, and wherein accessing the drug delivery port (32) comprising introducing a therapeutic agent through the needle (12) into the drug delivery port (32) comprising a septum (68) and the needle pierces (12) the septum (68) to access the port, and wherein the drug delivery device is a catheter (30), (col. 4 line 23. and figures 1-4).

It would have been obvious to one having ordinary skill in the art at the time of invention by applicant to modify the device of Vaslow by incorporating the method of the type taught by Luther et al in order to allow a sealed, safe manner in which to administer a therapeutic agent.

Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Vaslow in view of Gross U.S. Patent Number 5,843,048. Vaslow discloses the device as described above with reference to claim 1, but fails to explicitly disclose the method step of delivery of a therapeutic agent to a spinal column.

Gross discloses a similar device and a method including; a method of delivering a therapeutic agent to a spinal column comprising: providing a drug delivery device (22)

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containing a therapeutic agent and comprising the needle at a distal portion thereof; and introducing the therapeutic agent through the needle into a spinal column (col. 7 line 2).

It would have been obvious to one having ordinary skill in the art at the time of invention by applicant to modify the device of Vaslow by incorporating the method of the type taught by Gross et al in order to allow delivery to the spinal cord without additional coring.

Claims 22 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vaslow in view of Johnson U.S. Patent Number 5,817,052.

Vaslow discloses the device as described above with reference to claim 1, but fails to explicitly disclose the method step of collecting a fluid sample creating a vacuum.

Johnson discloses and a method including; a method of collecting a fluid sample from a body comprising: providing a drug delivery device comprising the needle at a distal portion thereof, inserting the needle into a fluid containment site of a body; and creating a vacuum in the drug delivery device to collect a fluid sample from the fluid containment site of the body, (col. 19 line 40) and the fluid sample consists of blood, (col. 19 line 7).

It would have been obvious to one having ordinary skill in the art at the time of invention by applicant to modify the device of Vaslow by incorporating the method of the type taught by Johnson in order to safely withdraw fluids.

Response to Arguments

Applicant's arguments filed on August 16, 2006 have been fully considered but they are not persuasive. Applicant argues that Vaslow fails to disclose a curvilinear distal end. However

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as described above the distal most end is a curvilinear distal tip (see line of curvature of 20 from point marked by 8 to point marked by 14 and inward arc).

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

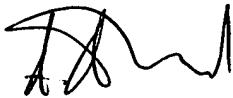
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Aamer S. Ahmed whose telephone number is 571-272-5965. The examiner can normally be reached on Monday thru Friday 9-5.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



A. Ahmed



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